REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated December 16, 2004 are respectfully requested. Applicants thank the Examiner for an indication that claims 10-19 are allowed.

I. Rejection under 35 U.S.C. §102

Claims 1-7 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Cosman *et al.* (U.S. Patent No. 6,530,922).

These rejections are respectfully traversed.

A. The Present Invention

The present invention, as embodied by claim 1, describes a method of controlling an ablation volume depth during surface treatment comprises (a) providing an apparatus, where the apparatus comprises (i) a housing having a proximal end and a distal end including a tissue contacting surface having at least one aperture, and the housing defines an interior, (ii) an energy delivery device including a plurality of electrodes, each with a tissue penetrating distal end, the plurality of electrodes configured to be advanced from the housing interior through the at least one aperture and into a target tissue site to define an ablation volume at least partly bounded by the tissue surface, (iii) an advancement device coupled to the energy delivery device, where the advancement device is configured to selectively advance individual electrodes of the plurality of electrodes from the housing interior to a selected deployment depth. The method further comprises (b) positioning the tissue contact surface on a target tissue surface, (c) selectively advancing the plurality of electrodes using the advancement device to the selected deployment depth beneath a tissue surface while avoiding a critical structure, (d) delivering ablative energy from the energy delivery device (e) creating an ablation volume at a controlled depth below the tissue surface responsive to the electrode advancement device, and (f) minimizing injury to the critical structure responsive to the electrode deployment depth.

B. The Prior Art

COSMAN ET AL. describe a device for ablation of tissue. The device generally includes a cluster or array of electrodes. Various embodiments of the device are described. In one embodiment (Fig. 7, Col. 12, lines 20-47), the device includes electrodes attached to a plunger hub, which slides in a carrier or sheath. As the plunger hub is advanced, the cluster of electrodes is inserted into an organ.

In another embodiment, illustrated in Fig. 10 (Col. 15, lines 24-45), the ablation device contains three electrodes that are inserted into an organ using a guide block. (Col. 15, lines 42-44). The guide block serves to direct the electrodes to the desired site within the tumor, the electrodes being advanced in this embodiment by manual insertion. Manual insertion of the electrodes obviously does not involve an advancement member.

C. Analysis

According to the M.P.E.P. § 2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference".

A rejection under 35 U.S.C. § 102 is proper only when the claimed subject matter is identically disclosed or described in the prior art. The Court of Appeals for the Federal Circuit has stated that "the [lower] court erred in considering that separate disclosures in different parts of a multiple volume treatise ... can be combined to find anticipation". *North American Oil Co., Inc. v. Star Brite Distributing, Inc.*, 46 Fed. Appx. 629, 631 (Fed. Cir. 2002) (unpublished).

For the instant rejection to be proper, the Cosman *et al.* reference must clearly and unequivocally disclose the claimed method, or direct those skilled in the art to the claimed method, without any need for picking, choosing, and combining various disclosures within the cited reference. Such picking and choosing may be entirely proper in the making of an obviousness rejection, where the applicant must be afforded an opportunity to rebut with objective evidence any inference of obviousness which may arise from the similarity of the subject matter which he

claims to the prior art, but it has no place in the making of a anticipation rejection under 35 U.S.C. 102 rejection. *Application of Arkley*, 455 F.2d 586, 587-8 (CCPA 1972).

The method of instant claim 1 includes providing an apparatus comprising an advancement device that is configured to selectively advance individual electrodes from the housing interior to a selected deployment depth.

Cosman *et al.* fail to teach this claim element. Specifically, Cosman *et al.* nowhere show providing an apparatus that comprises an advancement device configured to selectively advance individual electrodes of a plurality of electrodes from a housing interior to a selected deployment depth.

The Examiner points to Col. 15, lines 42-45 as a teaching of an advancement device that is configured to selectively advance individual electrodes. This assertion is untenable. The cited passage refers to the embodiment shown in Figure 10 where three electrodes are positioned in a guide block that is placed against the patient's head. The electrodes are inserted in sequential or parallel fashion "using free hand, stereotactic guide block, digitizer navigator, or ultrasonic, MRI, or CT control" (Col. 15, lines 42-45). None of these insertion aids are an advancement device, much less an advancement device configured to selectively advance individual electrodes, as discussed below.

A stereotactic guide block is a frame for use with frame-based electrode navigation systems requiring an external localization system on a frame rigidly fixed to a patient's head during the data acquisition phase. Free-hand navigation does not require a rigidly fixed frame, but uses a referencing technique, such as skull fixation markers placed into the skull or non-invasive external reference markers fixed to the skin. In both the stereotactic guide block technique and the free-hand navigation system the electrodes are manually inserted based on the navigation provided by the stereotactic guide or the free-hand references. No advancement device is used.

The digitizer navigator, ultrasonic, MRI and CT are each imaging tools used for placement of the electrodes. None of these teach an advancement device element of the apparatus provided.

Thus, the passage cited by the Examiner fails to teach providing an apparatus comprising an advancement device.

Figure 11 of Cosman *et al.* (Col. 15, lines 46-62) teaches the use of an integral hub to fix the electrodes in a parallel geometry. The integral hub is used to manually insert the electrodes in parallel. However, the integral hub cannot be said to teach an advancement device as the integral hub is manually pushed to deploy the electrodes. Even if the Examiner is of the mind that the integral hub teaches an advancement device, the hub still fails to teach providing an apparatus comprising an advancement device configured to selectively advance individual electrodes as the proximal ends of the electrode shafts are "fixed mechanically" in the integral hub (Col. 15, lines 57-59).

The **only** advancement device described by Cosman *et al.* is the plunger unit as seen in Fig. 7 (Col. 12, lines 20-47). In this embodiment of Cosman *et al.*, the plunger hub is a single unit that advances each electrode in the array of electrodes at the same time (i.e. in unison) and to the same depth into the organ. This is evidenced by the statement in Cosman *et al.* that "[i]n this way, the carrier may be manually held to the organ surface, and the electrodes 130 and 131 pushed in unison into the tissue to show that their tips 132 and 133 reach the targeted volume 135" (emphasis added, see Col. 12, lines 34-38). Thus, the plunger unit of Cosman *et al.* **cannot** selectively advance individual electrodes as presently claimed.

Examiner's Arguments

The Examiner states "[a] stereotactic guide is considered by the Examiner to be an advancement device" (Office action mailed December 16, 2004, page 3).

Applicants' Rebuttal

As described by the Neurosurgical Medical Clinic (www.sd-neurosurgeon.com/practice/stereotactic.html, visited on March 16, 2005, copy enclosed) it is well-known to those of skill in the art, that a stereotactic guide block is a frame used in frame-based stereotactic surgery. The frame is physically attached to

the patient with pins to provide an external, three-dimensional frame of reference for use with CT or MRI imaging. The electrodes are manually inserted with the guidance of the frame to precisely position the electrodes. Therefore, the stereotactic guide block of Cosman *et al.* cannot be relied upon for a teaching of an advancement member, much less an advancement member configured to selectively advance individual electrodes.

Thus, Cosman *et al.* fail to teach each and every element as set forth in the claim is found, either expressly or inherently as required to support a rejection under 35 U.S.C. 102. Accordingly, Applicants submit that standard of strict identity to maintain a rejection under 35 U.S.C. § 102 has not been met and withdrawal of the rejections under 35 U.S.C. § 102(e) is respectfully requested.

II. Rejections under 35 U.S.C. §103

Claims 8, 9, and 20 were rejected under 35 U.S.C. §103 as allegedly obvious over Cosman *et al.* further in view of Behl *et al.* (U.S. Patent No. 6,337,998). This rejection is respectfully traversed.

A. The Present Invention

The instant method, according to claims 8 and 9, is described above. The method according to claim 20 includes a step of providing a tissue surface treatment apparatus comprising an advancement device coupled to the energy delivery device, the advancement device configured to selectively advance individual electrodes of the plurality of electrodes from the housing interior to a selected deployment depth.

B. The Prior Art

COSMAN ET AL. is described above.

BEHL ET AL. describe a system for treatment of target region beneath a tissue surface comprising a probe for deploying an electrode array within the tissue and a cover for engaging the tissue surface above the treatment site. The cover may be a

rigid plate and may be clipped or otherwise removably attached to the probe. The cover may comprise electrode(s) or be electrically neutral.

Analysis

According to the MPEP § 2143, one of the three basic criteria that must be met to establish a prima facie case of obviousness is that the prior art references (or references when combined) must teach or suggest all the claim limitations.

As noted above, Cosman *et al.* fail to teach providing a tissue surface treatment apparatus including an advancement device, where the advancement device is configured to selectively advance individual electrodes of the plurality of electrodes from the housing interior to a selected deployment depth.

The teaching in Behl *et al.* does not make up for this deficiency. The system of Behl *et al.* includes (i) a probe for deploying an electrode array at a tissue site and (ii) a surface electrode for engaging the tissue surface above the treatment site.

As seen in Fig. 6A, the electrodes of the electrode array are uniformly deployed from the distal tip of the probe. Thus, the probe of the treatment system cannot be said to teach providing tissue surface treatment apparatus including an advancement device, where the advancement device is configured to selectively advance individual electrodes of the plurality of electrodes.

As further seen in Fig. 6A, nor does the surface electrode show an advancement device capable of selectively advancing a plurality of surface electrodes from at least one aperture in a housing. The surface electrode comprises an electrically conductive plate having a plurality of tissue-penetrating pin electrodes projecting forwardly from the face of the plate (Col. 12, lines 44-47). As described on Col. 13, lines 17-19, the surface electrode is advanced toward the tissue surface to penetrate the tissue with the electrode pins. The pins are attached directly to the plate and, therefore, the surface electrode does not even include an advancement device, much less an advancement device configured to selectively advance individual electrodes.

Accordingly, neither the probe nor the surface electrode of the Behl *et al.* system teach a step of providing a tissue surface treatment apparatus including an advancement device, where the advancement device is configured to selectively advance individual electrodes of the plurality of electrodes from the housing interior to a selected deployment depth.

Because neither of the references, alone or in combination, teach all the claim limitations of the present invention, the standard for obviousness has not been met. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

III. CONCLUSION

In view of the foregoing, Applicants submit that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

The Examiner is invited to contact Applicants' representative at (650) 838-4410 if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

Jacqueline F. Mahoney

Date: March 16, 2005

Jacqueline F. Mahoney
Registration No. 48,390

Correspondence Address:
Customer No. 22918
(650) 838-4300